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COMPARATIVE STUDY OF THE EFFECT OF TILANALA KSHARA IN THE MANAGEMENT OF VATASTHILA

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ABSTRACT
Benign prostatic hyperplasia is among the most common urological diseases in men and estimated to be 26.2% in men between the age group of 40-60 and above. There is a benign overgrowth of prostatic tissue resulting in lower urinary tract symptoms. The condition further leads to interference in daily activity of patients and create a negative impact on the quality of life. The management of BPH can be done by medical and surgical interferences but they are associated with few limitations. Ayurveda has its own principles in treating the condition, among which use of Kshara is one of them. The present clinical study deals with administration of Tilanala Kshara in the patients with clinical presentation of BPH, along with comparative analysis in the patients by administrating Tamsulosine Hydrochloride. The assessment score using International Prostate Symptom Score (IPSS) was carried out for changes in the subjective parameters. An effort has been made to evaluate the efficacy of Tilanala Kshara in patients with BPH, so that it can be used as an alternative treatment protocol for the disease BPH.

KEYWORDS: Benign Prostatic Hyperplasia, Mutraghata, Vatasthila, Tilanala Kshara, IPSS.

INTRODUCTION
Ayurveda, the science of life is a unique gift of Lord Brahma to the mankind, which is considered as the oldest remedial source of medicinal science. The *Rigveda* and *Atharvaveda* are the chief sources of information regarding medicine during Vedic period. There are around 10572 hymns in *Rigveda* discussing chiefly about *Tridoshas* along with description of organ transplant, plastic surgery, use of herbs and minerals to heal diseases etc. In *Atharvaveda*, around 5977 hymns discuss the anatomy, physiology and surgery.[1] The earliest description about the afflictions of urinary tract can be traced as far back as *Atharvaveda* [Ref. Ath.V-1-1/316-9].The disease *Prameha* comes under the first group whereas *Ashmari*, *Mutrakricchra* and *Mutraghata* fall under the second. Acharya Dalhana, Chakrapani, and Vijayarakshita have demarcated the difference between them which is based on the intensity of "*Vibhanda*" or "*Avarodha*" (obstruction) which is more pronounced in *Mutraghata*.

Benign prostatic hyperplasia is one of the most common urological diseases affecting millions of men worldwide. The pooled prevalence of BPH worldwide is estimated to be 26.2%, where the prevalence is 14.8 % in younger males aged 40 and it is 36.8 % in males aged 80 and above. It is characterized by a benign overgrowth of prostatic tissue around the urethra which ultimately constricts the urethral opening, resulting in lower urinary tract symptoms. The symptoms associated with LUTS include Urgency, Frequency, Nocturia, Incomplete Urination and Weak Stream.[2] The condition is associated with interference in daily activity of patients to produce a negative impact on quality of life. Many other complications associated with BPH include acute urinary retention, chronic urinary retention, Urinary Tract Infections (UTIs), formation of bladder calculi, hematuria and damage to bladder walls and kidneys.[3] The management of BPH is divided into conservative, medical and surgical with latest technological advances but each of them has its own limitations. Approximately, 10% of patients who have undergone Transuretheral Prostectomy or open Prostectomy for BPH has subsequently develop cancer.[4] Although, surgery is the choice for treatment, but due its expensiveness and number of complications, Ayurvedic approach towards the disease can provide promising results.

In the classics Acharya Sushruta decided general line of management of all types of Mutraghata by use of Kashaya, Kalka, Avaleha, Kshar, Madya, Asava, Swedana, Basti and Uttarbasti. Hence, in the present dissertation, an attempt has been made to use Tilanala kshara in managing the disease, so that it can be used as a treatment modality in the management of BPH.

AIM AND OBJECTIVES

Aim

To study the Effect of Tilanala Paniya Kshara in the management of Vatasthila, with special reference to Benign Prostate Hyperplasia.

Objectives

Evaluate the effect of Tilanala Paniya Kshara in the management of Vatasthila with special reference to Benign Prostate Hyperplasia. To observe any adverse effect (if any) of TilanalaKshara when administered orally in patients suffering from Vatasthila with special reference to Benign Prostate Hyperplasia.

MATERIALS AND METHODS

Clinical research is the prime aim of medical researches. Any study is incomplete without its assessment towards its prime aim and that is its clinical efficacy in terms of clinical study.

MATERIAL

1) Procurement, Authentification And Standardization

Tila Panchanga was collected in the month of July, 2018, from the fields of Ringas district Sikar, Rajasthan, India. It was authenticated at Dept. of Botany, Savitribai Phule Pune University.

2) Preparation of Drugs

The Tilanala Kshara was prepared as per the guidelines mentioned in classics and standardized at Dept. of Botany, Savitribai Phule Pune University, Pune, prior to use in clinical study. After preparation of Tilanala Kshara, the standardization was carried out for its Organoleptic and Physico-chemical parameters at Dept. of Botany, Savitribai Phule Pune University, Pune.

SELECTION OF PATIENTS

Patients were classified into 2 groups

Group A (Trial Group) – 30 patients for experiment of Tilanala kshara, 500 mg half an hour before meal.

Group B (Control Group) – 30 patients were selected for Tamsulosine Hydrochloride, 0.4 mg one hour before sleep.

Patients were selected from OPD and IPD of Shalyatantra department, Bharati Ayurved Hospital, Pune 43. Patients were carefully examined including Inspection palpation and systemic examination as per proforma. After taking proper history the diagnosis of BPH was confirmed by per rectal examination.

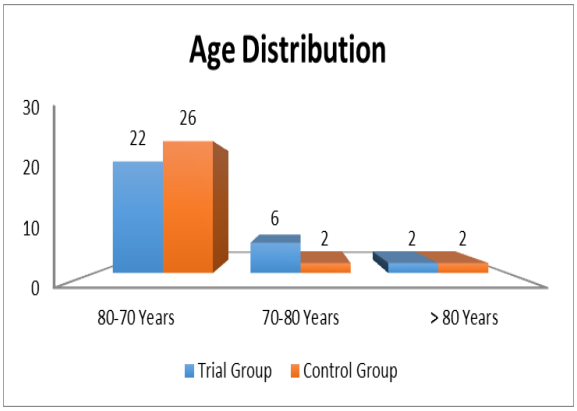
OBSERVATIONS AND RESULTS

Total 65 patients were registered in this clinical study which was divided into 2 groups.

Groups	Registered	Completed	Dropped
Trial group	33	30	3
Control group	32	30	2

Age wise distribution of 30 patients of Vatasthila

Age Group	Trial Group		Control Group	
	Frequency	Percentage	Frequency	Percentage
60-70 Years	22	73.3	26	86.7
70-80 Years	6	20.0	2	6.7
> 80 Years	2	6.7	2	6.7
TOTAL	30	100.0	30	100.0

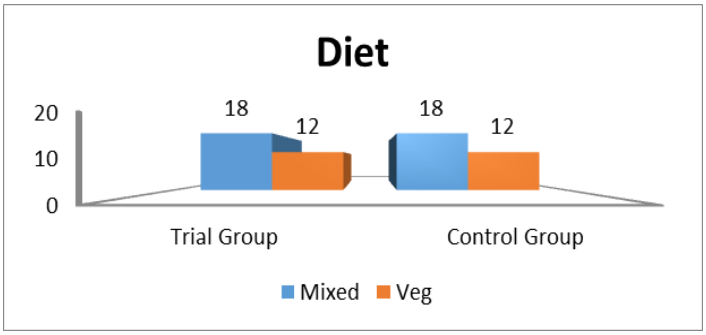


Graph 1: Age wise distribution of 30 patients of Vatasthila.

Out of the 60 patients selected for this study, 48 patients belong to the age group of 60 - 70 years [80%] followed by 8 patients [13.35%] were in the age group of 70 - 80 years and 4 patients [6.7%] were in more than 80 years age group respectively.

Diet wise distribution of 60 patients of Vatasthila

Diet	Trial Group		Control Group	
	Frequency	Percentage	Frequency	Percentage
Mixed	18	60.0	18	60.0
Veg	12	40.0	12	40.0
TOTAL	30	100.0	30	100.0

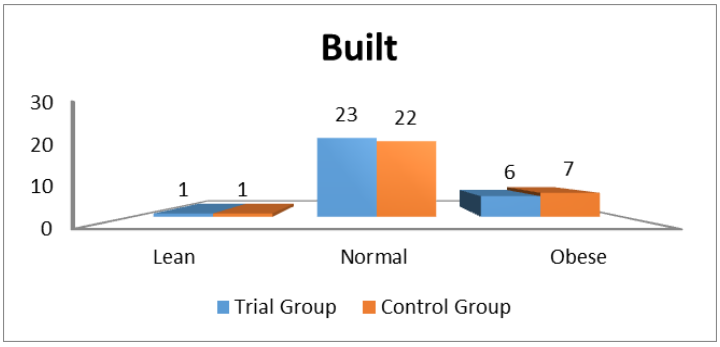


Graph 2: Diet wise distribution of 60 patients of Vatasthila.

60% patients were used to take mixed diet whereas 40% patients were habituate to take vegetarian diet.

Body-built wise distribution of 60 patients of Vatasthila.

Built	Trial Group		Control Group	
	Frequency	Percentage	Frequency	Percentage
Lean	1	3.3	1	3.3
Normal	23	76.7	22	73.3
Obese	6	20.0	7	23.3
TOTAL	30	100.0	30	100.0

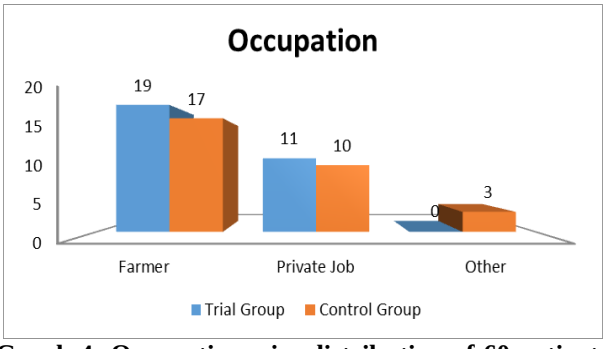


Graph 3: Body-built wise distribution of 60 patients of Vatasthila.

Out of 60 patients, 2 patients [3.3%] were having lean body-built, 55 patients [75%] were having normal body-built and 13 patients [21.65%] were obese.

Occupation wise distribution of 60 patients of Vatasthila

Occupation	Trial Group		Control Group	
	Frequency	Percentage	Frequency	Percentage
Farmer	19	63.3	17	56.7
Private Job	11	36.7	10	33.3
Other	0	0.0	3	10.0
TOTAL	30	100.0	30	100.0



Graph 4: Occupation wise distribution of 60 patients of Vatasthila.

On considering the nature of occupation it was observed that 36 patients [60%] were in farmers while 21 patients [35%] were in private service and 3 patients [10%] were engaged in other occupations respectively.

EFFECT OF THERAPY

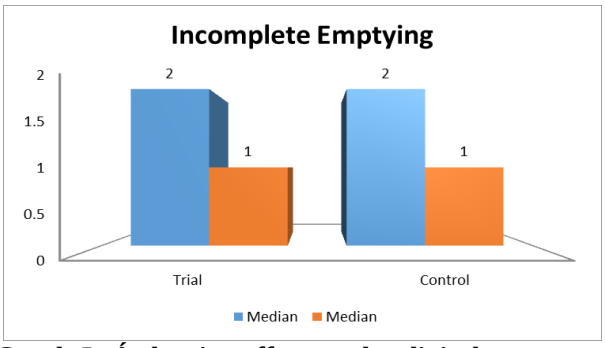
Total 60 numbers of patients were examined.
The patients were divided into two groups-

1. Trial Group: Tilanala kshara
No. of patients -30

2. Control Group (Tamsulosin Hcl 0.4mg)
No of patients -30

Effect of therapy on individual clinical parameters is as follows –
Showing effect on the clinical parameter of incomplete emptying.

Incomplete Emptying	Median		Wilcoxon Signed Rank W	P-Value	% Effect
	BT	AT			
Trial	2	1	-3.704[a]	0.000	36.1
Control	2	1	-4.021[a]	0.000	39.7

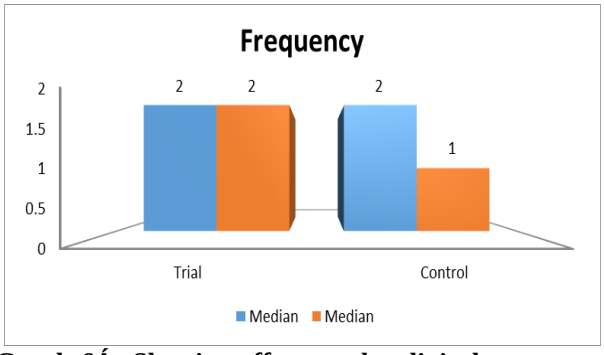


Graph 5: Á showing effect on the clinical parameter of incomplete emptying.

The effect of therapy on the clinical feature of incomplete emptying was 36.1% in trial group and 39.7% in control group respectively. There was significant improvement in both the groups with p-value <0.05, but it was more significant in control group.

Showing effect on the clinical parameter of frequency.

Frequency	Median		Wilcoxon Signed Rank W	P-Value	% Effect
	BT	AT			
Trial	2	2	-3.787[a]	0.000	31.4
Control	2	1	-4.122[a]	0.000	44.6

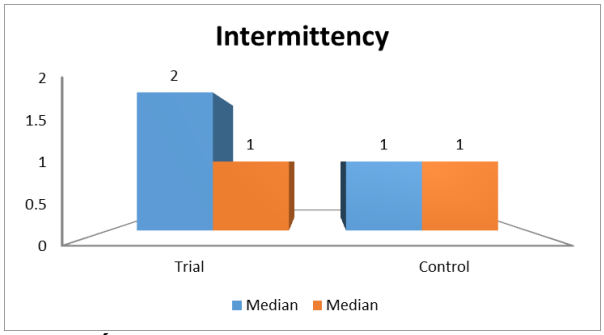


Graph 6Á: Showing effect on the clinical parameter of Frequency.

The effect of therapy on the clinical feature of frequency was 31.4% in trial group and 44.6% in control group respectively. There was significant improvement in both the groups with p-value <0.05, but it was more significant in control group.

Showing effect on the clinical parameter of Intermitency.

Intermittency	Median		Wilcoxon Signed Rank W	P-Value	% Effect
	BT	AT			
Trial	2	1	-3.700[a]	0.000	35.6
Control	1	1	-2.358[a]	0.018	25.5

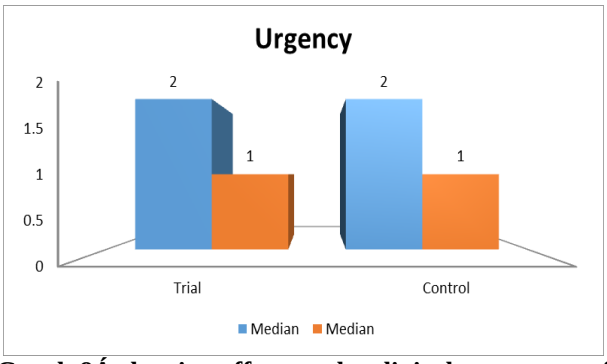


Graph 7Á: Showing effect on the clinical parameter of Intermittency.

The effect of therapy on the clinical feature of intermittency was 35.6% in trial group and 25.5% in control group respectively. There was significant improvement in both the groups with p-value <0.05, but it was more significant in trial group.

Showing effect on the clinical parameter of Urgency.

Urgency	Median		Wilcoxon Signed Rank W	P-Value	% Effect
	BT	AT			
Trial	2	1	-3.354[a]	0.001	31.6
Control	2	1	-4.044[a]	0.000	41.0

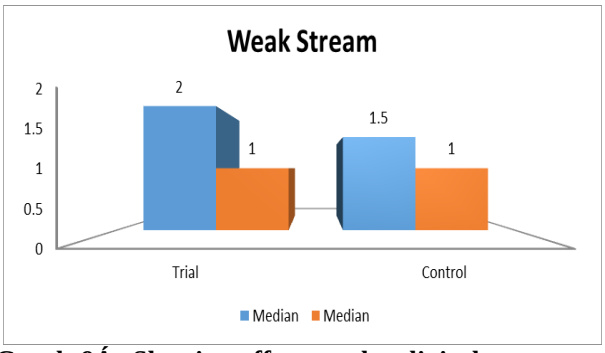


Graph 8Á showing effect on the clinical parameter of Urgency.

The effect of therapy on the clinical feature of urgency was 31.6% in trial group and 40.0% in control group respectively. There was significant improvement in both the groups with p-value <0.05, but it was more significant in control group.

Showing effect on the clinical parameter of Weak stream.

Weak stream	Median		Wilcoxon Signed Rank W	P-Value	% Effect
	BT	AT			
Trial	2	1	-2.676[a]	0.007	25.0
Control	1.5	1	-2.994[a]	0.003	36.0

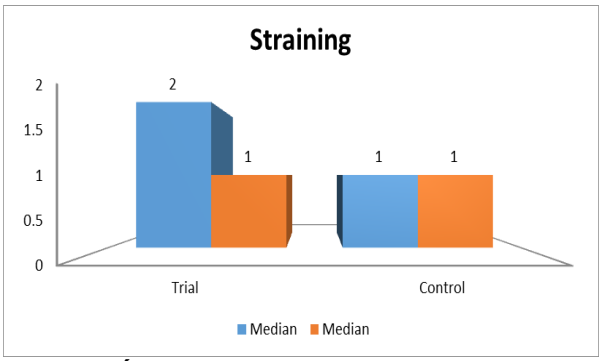


Graph 9Á: Showing effect on the clinical parameter of Weak stream.

The effect of therapy on the clinical feature of weak stream was 25.0% in trial group and 36.0% in control group respectively. There was significant improvement in both the groups with p-value <0.05, but it was more significant in control group.

Showing effect on the clinical parameter of Straining.

Straining	Median		Wilcoxon Signed Rank W	P-Value	% Effect
	BT	AT			
Trial	2	1	-3.095[a]	0.002	32.6
Control	1	1	-2.556[a]	0.011	25.0

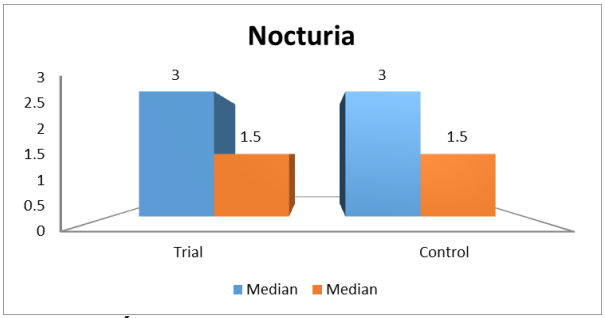


Graph 10Á showing effect on the clinical parameter of Straining.

The effect of therapy on the clinical feature of straining was 32.6% in trial group and 25.0% in control group respectively. There was significant improvement in both the groups with p-value <0.05, but it was more significant in trial group.

Showing effect on the clinical parameter of Nocturia

Nocturia	Median		Wilcoxon Signed Rank W	P-Value	% Effect
	BT	AT			
Trial	3	1.5	-4.284[a]	0.000	43.8
Control	3	1.5	-4.467[a]	0.000	46.4

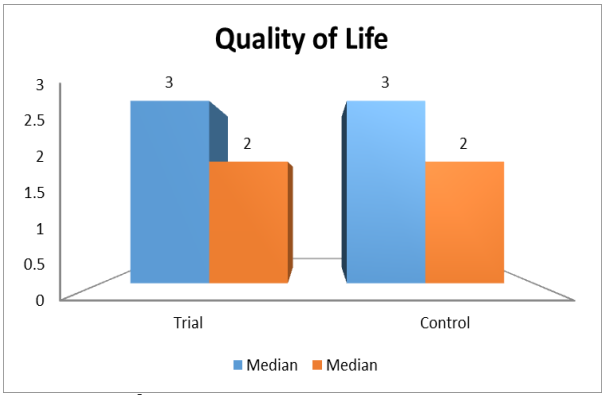


Graph 11Á showing effect on the clinical parameter of Nocturia.

The effect of therapy on the clinical feature of Nocturia was 43.8% in trial group and 46.4% in control group respectively. There was significant improvement in both the groups with p-value <0.05, but it was more significant in trial group.

Showing effect on the of Quality of life

Quality of Life	Median		Wilcoxon Signed Rank W	P-Value	% Effect
	BT	AT			
Trial	3	2	-4.381[a]	0.000	41.5
Control	3	2	-4.562[a]	0.000	44.3



Graph 12: Á showing effect on Quality of Life.

The effect of therapy on the quality of life was 41.5% in trial group and 44.4% in control group respectively. There was significant improvement in both the groups with p-value <0.05, but it was more significant in control group.

The overall effect of therapy can be summarized as follows -

1. In trial group

43.80 % relief was observed in Nocturia followed by 36.10 % relief in Incomplete emptying, 35.60 % in intermitency, 32.60 % in Straining, 31.60 % in Urgency, 31.40 % relief in Frequency and 25.00 % in Weak urine stream. All these values were statistically highly significant (P<0.001).

2. In control group

46.40 % relief was observed in Nocturia followed by 44.60 % relief in Frequency, 41.00 % in Urgency, 39.70 % relief in Incomplete emptying, 36.00 % in Weak urine stream, 25.00 % in Straining and 25.5 % relief in intermitency and. All these values were statistically highly significant (P<0.001).

The result of the therapy in both the groups has shown significant result with p value less than 0.001.
Showing comparison between Trial Group and Control Group

	Group	N	Mean Rank	Sum of Ranks	Mann-Whitney U	P-Value
Incomplete Emptying	Trial	30	28.92	867.50	402.500	0.449
	Control	30	32.08	962.50		
	Total	60				
Frequency	Trial	30	27.53	826.00	361.000	0.160
	Control	30	33.47	1004.00		
	Total	60				
Intermitency	Trial	30	33.05	991.50	373.500	0.222
	Control	30	27.95	838.50		
	Total	60				
Urgency	Trial	30	26.92	807.50	342.500	0.084
	Control	30	34.08	1022.50		
	Total	60				
Weak stream	Trial	30	29.50	885.00	420.000	0.617
	Control	30	31.50	945.00		
	Total	60				
Straining	Trial	30	31.28	938.50	426.500	0.703
	Control	30	29.72	891.50		
	Total	60				
Nocturia	Trial	30	29.13	874.00	409.000	0.516
	Control	30	31.87	956.00		
	Total	60				
Quality of Life	Trial	30	30.13	904.00	452.000	0.551
	Control	30	32.87	986.00		
	Total	60				

For comparison between Trial Group and Control Group, we have used Mann Whitney U test. From above table we can observe that P-Values for all parameters are greater than 0.05. Hence we conclude that there is no significant difference between Trial Group and Control Group.

DISCUSSION

The obtained observations and results are as discussed below:-

1. Age

A higher incidence of the condition of BPH was found in the Age group 60-70 years (48 patients - 80%) followed by 70-80 year age group (8 patients – 13.35%). This reveals that the disease has tendency to afflict the ageing male, there by supporting the finding that there is an increased accumulation of 5- alpha- dihydrotestosterone (DHT) due to an age related shift in Prostatic androgen metabolism. In addition, age related changes in the ratio of Oestrogen : Androgen may contribute to the maintenance of BPH. Thus, age definitely seems to have a role in the manifestation of BPH.

According to Ayurveda also, Vata predominates in this age & therefore more the likelihood of Mutraghata.

2. Dietary Habits

Out of 60 patients, 12 patients (40%) were vegetarians followed by 18 patients (60%) who were taking mixed diet. This reflects that there is nothing to do with the manifestation of the disease.

3. Body-Built

Out of 60 patients, 55 patients [75%] were having normal body-built followed by 13 patients [21.65%] were obese and 2 patients [3.3%] were having lean body-built. This shows there is no significant relationship of body-built with the disease, as it is more age-related problem.

4. Occupation

It was observed, that incidence of Benign Prostatic Hypertrophy is higher in farmers i.e. 60% and it was least found in person engaged in other sort of occupations i.e.10 %. It can be justified by means of principle of Ayurveda, that physical work leads to aggravation of Vata Dosha, which is considered having key role in development of disease.

RESULTS OF IPSS SCORING BEFORE AND AFTER TREATMENT

1. Incomplete Emptying: The effect of therapy was 36.1% in trial group and 39.7% in control group respectively. There was significant improvement in both the groups with p-value <0.05, but it was more significant in control group.

Since, the result in both the groups was comparable, it can be concluded that Tilanala kshara can be proved an effective alternate for Tamsulosine Hydrochloride. In BPH, the detrusor is unable to sustain the increased pressure until the end of voiding because of obstructive prostatic tissue at the bladder neck causing a "ball valve"

effect. The control drug Tamsulosine HCL, having affinity for adrenoceptors which causes smooth muscle in the prostate and bladder neck to relax, resulting in an improvement in urinary flow rate. It can be assumed that Tilanala kshara plays the same role.

2. Frequency: It was observed that there was 31.4% effect in trial group and 44.6% in control group respectively. There was significant improvement in both the groups with p-value <0.05. As the hypertrophied bladder muscle has a higher resting tonus so that smaller volumes of urine may initiate the desire to void.

The property of Kshara is Shodhana, Lekhana, Bhedana, Pachana and Tridoshagna properties; it may leads to scrapping of hypertrophied wall of bladder thereby improving the symptoms of frequency in the patients.

3. Intermittency: The effect of therapy was 35.6% in trial group and 25.5% in control group respectively, but it was more significant in trial group.

The detrusor muscle in BPH, is unable to sustain the increased pressure till the end of voiding. The property of Tilanala Kshara is Mutrajanana, which may facilitate to keep up the pressure of urine till voiding, thereby improving the symptoms of intermittency in patients.

4. Urgency: The effect of therapy on the clinical feature of urgency was 31.6% in trial group and 40.0% in control group respectively.

This is due to Detrusor instability and bladder spasm. The drug used in Tilanala Kshara has Rasayana property and it is believed to cause tonic effect to urinary bladder. This is highly helpful in strengthening the urinary bladder and improves the symptoms.

5. Weak Stream: The effect of therapy was 25.0% in trial group and 36.0% in control group respectively. There was significant improvement in both the groups with p-value <0.05

The symptoms are due to urethral compression which is one of the early and constant features of B.P.H. The drugs having Rasayan property along with mutrala guna can help in strengthing of urinary system, the force of urine gets improved. Thus Tilanala Kshara can be proved to be apt candidate for the improvement of the same symptoms.

6. Straining: The effect of therapy was 32.6% in trial group and 25.0% in control group respectively. There was significant improvement in both the groups with p-value <0.05, but it was more significant in trial group.

In BPH, there is residual urine which may causes straining in patients. If amount of residual urine is decreased, patient gets relief from the symptom. As per Ayurvedic science, Kshara has Vata Shamaka property which normalizes the function of Apana Vayu which is responsible for urinary functions. Thus, Tilanala Kshara, thereby corrects the urinary functions as well as due to mutral guna may leads to proper urinary passage. The symptom of Straining gets improved.

7. Nocturia: The effect of therapy was 43.8% in trial group and 46.4% in control group respectively. There was significant improvement in both the groups with p-value <0.05, but it was more significant in trial group.

The presence of an enlarged prostate provokes the bladder to trigger a voiding response more frequently than in normal individuals. As sphincteric tone is reduced during sleep so if one or two drops passes in to the sensitive urethral mucosa, patient has a desire to void the urine. As during night hours there is aggravation of Vata and Tilanala Kshara corrects the vitiated Vata and thereby leads to reduction in the symptom of nocturia.

8. Quality of Life: The effect of therapy was 41.5% in trial group and 44.4% in control group respectively. There was significant improvement in both the groups with p-value <0.05.

Since, the aim of therapy was to improve the Quality Of Life(QOL) by providing symptomatic relief and increasing maximum flow rate as well as reducing disease progression and the development of new morbidities. As there is significant improvement in the symptoms as well as the flow rate of urine is improved, it can be concluded that Tilanala Kshara can be effectively used in the management of the disease, thereby providing relief and improving the quality of life of elderly male patients

Analysis of International prostate Symptom Score

This is an internationally standardized criteria for judging symptoms throughout practical observations. Conclude that there is significant reduction in IPSS score both by Tilanala kshara and Tamsulosine hydrochloride.

The point to be desired is that both Tilanala kshara and Tamsulosine hydrochloride are equally efficient in Reducing International Prostate symptom score.

CONCLUSION

Vatasthila is among the group of Obstructive Uropathy named as Mutraghata. The disease is comparable to Benign Prostate Hyperplasia on the basis of symptoms.

Though many modes of treatment has been described in almost all ancient treatises. In the present study, the effect of Tilanala Kshara was studied along with a comparative analysis of the effect with the drug Tamsulosine Hydrochloride. The assessment was done using International prostate Symptom Score.

Using various statistical tools of analysis, it can be we can conclude that Tamsulosin i.e. control drug is more

efficient than Tilanala Kshara i.e. trial drug in present study. Though the result of the study was significant in both the groups, but it was more significant in control group. But, there was marked improvement in the symptoms of Intermittency, Straining and Nocturia as compared with the control drug.

Thus from above observations, the Tilanala Kshar can be the choice of drug in conservative Treatment of benign Prostratic Hypertrophy to reduce the symptoms mostly in Grade I and Grade II prostatomegaly.

It can be assumed that better result can be expected by increasing duration of treatment and other drugs can be incorporated along with the control drug.

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